PSJ9 Exh 17

U. S. Department of Justice
Drug Enforcement Administration
Detroit Field Division
431 Howard Street
Detroit, Michigan 48226
(313) 234-4000

www.dea.gov

FEB 2 6 2008

Michael Holmes, President
Lake Erie Medical and Surgical Supply
DBA: Quality Care Products LLC
6061 Telegraph Road, Suite I/J
Toledo, Ohio 43612

Dear Mr. Holmes:

Diversion Investigators (DIs) James Rafalski and Barbara Dobric of the Detroit office of the U.S. Drug Enforcement Administration (DEA) recently conducted a regulatory investigation of your firm. The regulatory investigation revealed recordkeeping and security violations. The violations noted are as follows:

1. Inventories performed did not contain complete and accurate records of all controlled substances. Retention samples resulting from the manufacturing process were not included in the inventories. Damaged controlled substances stock retained by the firm was not included in the inventories. The inventories performed did not contain whether the inventory was taken at the opening or closing of business. The firm presented a biennial inventory that was not clearly identified as the biennial inventory and did not indicate if it was taken at the opening or closing of business.

   Title 21 CFR Section 1304.11(a) requires each inventory contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. Section 1304.11(a) also requires that the inventory indicate whether it was taken at the opening or closing of business. Title 21 CFR Section 1304.11(c) requires an inventory of all stocks of controlled substances on hand be taken at least every two years.

2. The initial inventory was not properly documented. The firm did not provide Investigators with an initial inventory corresponding with the firm's addition of Schedule II controlled substances.

   Title 21 CFR Section 1304.11(b) requires an inventory of all stocks of controlled substances on hand on the date the firm first engages in the manufacture, distribution, or dispensing of controlled substances.

3. The firm did not have a sufficient system to disclose to the registrant suspicious orders of controlled substances.

   Title 21 CFR Section 1301.74 (b) requires the registrant to design and operate a system to disclose to the registrant suspicious orders of controlled substances.

This letter is formal notification that your failure to maintain adequate records and security for controlled substances constitutes violations of the Controlled Substances Act. At this time, you are being afforded the opportunity to comply with the requirements of the Controlled Substances Act which were outlined by DIs Rafalski and Dobric with the management of your firm.

Please advise this office in writing within thirty (30) days of the action taken or planned to correct these violations. If you have any questions concerning this matter, please contact Group Supervisor Abby Foster Hayes at (313) 234-4006.

Sincerely,

Robert L. Corso
Special Agent in Charge
Detroit Field Division